

Applicants: Quay et al.

Serial No.: 10/814,399

Filed: 3/31/2004

Title: CYANOCOBALAMIN LOW

VISCOSITY AQUEOUS FORMULATIONS FOR INTRANASAL DELIVERY Attorney Docket No.: 03-02CIP

1623

Group Art Unit:

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This SUPPLEMENTAL Information Disclosure Statement is submitted:

$\underline{\mathbf{X}}$	under 37 CFR 1.97(b), or
	(Within three months of filing national application; or date of entry of international
	application; or before mailing date of first office action on the merits; whichever occurs last)
	under 37 CFR 1.97(c) together with either a:
	Statement under 37 CFR 1.97(e), or
	a \$180.00 fee under 37 CFR 1.17(p), or
	(After the CFR 1.97(b) time period, but before final action or notice of
	allowance, whichever occurs first)
	under 37 CFR 1.97(d) together with a:
	Statement under 37 CFR 1.97(e), and
	a \$180.00 fee set forth in 37 CFR 1.17(p).
	(Filed after final action or notice of allowance, whichever occurs first, but
	before payment of the issue fee)

X Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

Respectfully submitted,

Paul G. Lunn

Attorney/Agent for Applicant(s)

Reg. No. 32743

Date: January 21, 2005

Telephone No.: (425) 908-3643 Facsimile No.: (425) 908-3655

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Date of Deposit: January 21, 2005

Typed Name: Jeffrey L. Granger

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PTO/SB/08a (08-03)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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Application Number	10/814,399					
Filing Date	03/31/2004					
First Named Inventor	Steven C. Quay et al.					
Art Unit	1623					
Examiner Name						
Attorney Docket Number	03-02CIP					

	U.S. PATENT DOCUMENTS										
Examiner Initials*	Cite No.1	Document Number Number - Kind Code ^{2 (# known)}	Issued Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear						
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FOREIGN PATENT DOCUMENTS									
Examiner Initials* Cite No. Foreign Patent Document Issue Date Name of Patentee or Applicant of Cited Document Name of Patentee or Name									
		CA 1,317,881	05-18-1993	Nastech Pharmaceutical Company Inc.					
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Examiner	Date	
Signature	Considered	

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Office, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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				Application Number	10/814,399		
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STATEMENT BY APPLICANT				First Named Inventor	Steven C. Quay et al.		
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(Use as many sheets as necessary)				Examiner Name			
Sheet	2	of	2	Attorney Docket Number	03-02CIP		

NON PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No.		T ²					
		U.S. Department of Health and Human Services, (Draft) Guidance for Industry, Bioavailability and						
		Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action, April 2003, pages 1-36 + attachments, U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Biopharmaceutics.						

Examiner	-	Date	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation it not in conformance and not considered. Include copy of this form with next communication to applicant.

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			Application Number	10/81	4,399
V)	TRANSMITTAL		Filing Date	Mar 3	31, 2004
	FORM		First Named Inventor	Quay	, Steven C.
	(to be used for all correspondence after initial filing)		Art Unit	1623	
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	Total Number of Pages in This Submission		Attorney Docket Number	03-02CIP	
		ENC	LOSURES (Check all th	at apply)
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Supplemental Information Disclosure Statement, one foreign patent and one literature document Certified Copy of Priority Document(s) Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53		Rem		mber of CD(s)			
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Jertey L. Granger

Date

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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO**: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**.